

2



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,912	11/18/2003	Martin C. Hinz	H76.2-11128US01	5651
24113	7590	04/11/2006	EXAMINER	
PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A. 4800 IDS CENTER 80 SOUTH 8TH STREET MINNEAPOLIS, MN 55402-2100			LAMM, MARINA	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/715,912

Applicant(s)

HINZ, MARTIN C.

Examiner

Marina Lamm

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/3/04; 6/8/05; 11.</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the Interview Summary, Terminal Disclaimer, IDS and Petition to withdraw Terminal Disclaimer, all filed 2/13/06. Claims pending are 29-35. (The Applicant is reminded that Claims 38-44 have been renumbered as Claims 29-35 pursuant to Rule 1.121)

Claim Objections

1. Claims 29 and 35 are objected to because of the following informalities: (1) the comma is missing between "Tyrosine" and "wherein" in line 5 of Claim 1; (2) Claim 1 does not end with the period; (3) the word "by" is missing between "divided" and ".8929" in line 9 of Claim 35. Appropriate corrections are required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 29-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 29 introduces new matter as it uses the phrase "for a patient not suffering from depression". There is no support in the specification for the employment of the phrase "not suffering from depression" in the

Art Unit: 1616

claims. The specification states that the method of the invention "is highly effective in resolving additional problems caused by or associated with obesity such as

...depression,...and other associated obesity related problems." See p. 7, lines 10-13.

However, the claimed method to facilitate weight loss "for a patient not suffering from depression" was not described in the application as filed, and persons skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. Therefore, it is the examiner's position that the disclosure does not reasonably convey that the inventor has possession of the subject matter of Claim 29 at the time of filing of the instant application. In summary, the instant claims now recite the method which was not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitation recited in the present claims, which did not appear in the specification, as filed, introduces a new concept and violates the description requirement of the first paragraph of 35 U.S.C. 112. Applicant is required to cancel the new matter in the response to this Office action. Alternatively, the Applicant is invited to point out to the parts of the specification which provide sufficient written support for the above-mentioned patient population. See MPEP 714.02 and 2163.06.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

Art Unit: 1616

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 29-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-48 of copending Application No. 11/157,198 ('198). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention overlaps with that previously claimed. Thus, claims of the instant application are directed to a method to facilitate weight loss for a patient not suffering from depression, said method comprising: (A) administration of Citalopram; (B)

Art Unit: 1616

administration of Diethylpropion; and (C) administration of 5-Hydroxytryptophan and Tyrosine at the specified dosage for the specified period of time. The method of the instant invention may further comprise the administration of Phentermine, Vitamin B6, Vitamin C and/or multivitamin, calcium and Lysine. Claims of the copending application '198 recite a method of treating weight dysfunction for a patient not suffering from depression, said method comprising: (a) administration of 5-Hydroxytryptophan; and (B) administration of Tyrosine in an effective therapeutic range. The method of '198 may further comprise the administration of vitamin B6, vitamin C, Calcium, lysine, Citalopram, Phentermine, and/or Diethylpropion. Thus, the conflicting claims substantially overlap in scope as discussed above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,527,788 (teaches using diethylpropion as an anorectic drug); US 6,207,699 (teaches using 5-HTP for treating obesity and reducing weight); US 6,323,236 (teaches using citalopram for treating eating disorders); GB 2137493 A (teaches using diethylpropion as an appetite suppressant); EP 347 066 A1 (teaches using citalopram as an antidepressant and in the treatment of obesity).
7. No claim is allowed at this time.

Art Unit: 1616

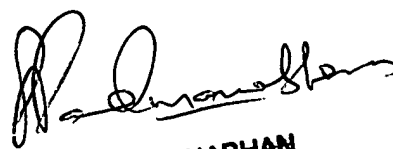
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm
3/29/06


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER


BRUCE KISLIUK, DIRECTOR
TECHNOLOGY CENTER 1600